



UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: G. SMALL Confirmation No.: 6750
Application No.: 09/972,802 Group Art Unit: 3732
Filing Date: October 9, 2001 Examiner: Pedro Philogene
For: UMBILICAL CORD CLAMP AND Attorney Docket No.: 104410-100
METHODS OF USING SAME

DECLARATION OF GEORGE H. SMALL, M.D., M.P.H. UNDER 37 C.F.R. § 1.132

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Commissioner for Patents
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Sir:

I, George H. Small, do declare that:

1. I am a United States citizen and currently reside at 1415 Cindee Lane, Colton, California 92324.

2. I received a Bachelor of Arts in Biology and a minor in Chemistry from Atlantic Union College in South Lancaster, Massachusetts in 1965. I received my M.D. from Temple University in 1974, and completed my residency in 1977. Then, I obtained a Masters in Public Health (M.P.H.) degree in Maternal and Child Health and Family Planning from Berkeley in 1978.

3. I have been practicing as a clinical OB/GYN for over 25 years. My employment history includes working as a clinical OB/GYN at the Inland Obstetrics and Gynecology Medical Group from 1980-1998; as clinical OB/GYN and Medical Director at the Loma Linda Community and Medical Group from 1995-1999; as clinical OB/GYN at the Metropolitan Medical Clinic from 1999-2003; and as a clinical OB/GYN and Medical Director of Palo Verde Medical Associates in Blythe, California from December 2004 to the present; with a brief sabbatical during part of 2003-2004.

4. I have reviewed and understand the above-identified patent application, the pending claims, the Office Action, and the references cited by the Examiner in the above-identified application. Specifically, these references are U.S. Patent No. 5,006,830 to Merritt ("Merritt") and U.S. Patent No. 6,132,447 to Dorsey ("Dorsey"). I am making the following statements as one of ordinary skill in the art in support of the patentability of claims 17-25 in this application.

5. Claims 17-25 of the above-identified application are directed to an umbilical cord clamp that includes a pair of arms each having a length in a generally V-shaped configuration having rear end portions joined together at the apex thereof and having free forward end portions normally disposed in spaced-apart relation and being movable towards each other to clamp an umbilical cord between the arms, identification means comprising a gender-identifying color associated with a portion of the clamp that is configured and adapted to facilitate identification of the gender of a baby while the clamp remains on the baby, and a locking portion for securing the arms together when the clamp is closed on the baby's umbilical cord. Methods of identifying the baby's gender, the baby, and inhibiting unauthorized removal of a baby, are also included.

6. Merritt teaches an umbilical cord clamp that contains a unique identification mark, which can include a serial code, bar code, color code, or letter combination. Each of Merritt's clamps must have a different distinctive mark on it. Merritt teaches to use the unique code to prevent unauthorized removal of a newborn from a pre-defined area. Merritt does not teach anything about identifying groups of children, or a gender-identifying means, or a gender-identifying color, or identifying the gender of a child. Rather, Merritt teaches only that a unique code of some sort is applied to the clamp to minimize child abductions from a pre-defined secured area, e.g., a post-natal ward. Also, Merritt does not address gender assurance from the baby's extraction from the mother through and beyond hospital discharge.

7. Dorsey teaches a decorative pair of blue, pink, green, or yellow-handled scissors labeled with birth-data and used to cut an umbilical cord, which are then whisked away to be cleaned, packaged, and presented to the baby's parents as a novelty gimmick. Dorsey does not suggest that the scissors should remain with the newborn, much

less in association with the umbilical cord, but instead teaches that the scissors are immediately removed from the baby's vicinity and separately packaged and provided in a nice display for the parents. Dorsey also does not teach to keep the presently recited gender-identifying color with the baby, or even to use its colors to identify the gender of the baby to facilitate gender-identification of the baby. Instead, Dorsey is simply a reminder to the parent's friends and relatives that they have a child of a particular gender, rather than providing a gender-identification means or color to or on the baby. Also, Dorsey does not teach that its colored scissors are actually attached to the baby, nor would they because Dorsey teaches to immediately clean the scissors after cutting the cord.

8. Merritt and Dorsey do not provide any motivation to take the typically blue or pink handle color of the Dorsey scissors, which are immediately removed from the baby's presence for cleaning and packaging, and the unique code or other identifier of Dorsey that is on an umbilical cord clamp to prevent unauthorized removal of the baby from a pre-set area. Actually, there would have been no reason to select the concept of colored-handles on the novelty scissors that are taken away from the child and combining them with the security devices of Merritt, because the Dorsey scissors were never meant to identify the baby's gender on the spot. Moreover, Dorsey teaches two main classes of colors, while Merritt teaches exactly the opposite—that unique selections of color codes or other unique indicia can be included on a clamp. Even when considering all their teachings together, Merritt and Dorsey still fail to teach putting a gender-identifying means on a baby or of identifying the baby's gender. Thus, they cannot teach my invention recited in claims 17-25.

9. On the contrary, the lack of a reliable, essentially error-free manner of determining the gender of a newborn baby without repeated undressing the baby has been a longstanding problem in the obstetric field. As of now, there are often embarrassing errors in misidentifying the gender of a baby for health care workers, parents, and visitors to the post-natal wards. In particular, many parents tend to be uptight, annoyed, or confused when their precious daughter is improperly categorized as a "he" and vice versa. One common solution for this problem prior to the invention, which is still typically in use today, involves use of blue or pink baby hats or other clothing. Unfortunately, many types of clothing such as hats tend to easily fall off of babies, and tend to be applied improperly when tired health care providers re-apply the hat or other colored clothing to a baby. Thus, not only do such hats or

clothing not always remain with the child, but the wrong color may be applied to the child at various times causing temporary confusion.

10. To the best of my knowledge, there has been no solution even to the present time of this problem of misidentifying the gender of newborn children while they are clothed. Most newborns in hospitals are still typically found wearing a diaper or a generic hospital shirt or jacket, which makes repeated and accurate gender-identification a problem. Based on my experience delivering children, the invention of Dorsey, or the alleged combination of Merritt and Dorsey, has not been adopted by anyone in the field. Thus, a solution was and is still required, which the surprising and unexpected invention presently recited in claims 17-25 solves.

11. The present invention elegantly solves this longstanding problem in the art by applying a gender-identifying clamp to a nude newborn at birth--when the chance for gender misidentification is significantly lower than later times when clothes are worn and gender errors are made. The clamp of the invention remains with the diapered-newborn baby until the umbilical cord stump falls off, which is generally after the baby departs from the hospital or other pre-defined area and typically takes about 1-2 weeks after birth. Thus, the clamp reduces risk and saves cost while improving patient, *i.e.*, the mother's, satisfaction. The inventive clamp will permit immediate and error-free gender-identification of babies even when a diaper or some clothing is being worn, and unlike Merritt and Dorsey, solves the long-standing in-patient problem of newborn gender identification.

12. Thus, it is my opinion and judgment, as one of ordinary skill in the art, there was and is no motivation to use Merritt's uniquely-coded umbilical cord clamps for gender-identifying means even in view of Dorsey's gender-colored novelty scissors. It would also not have been reasonably expected that colors from gender-colored scissors should be added to the security-coded clamps of Merritt to provide the different and surprising benefits of my claimed umbilical cord clamps and methods. Thus, the claimed invention provides a surprising advance that has been absent in the art and clinical medical practice management of a newborn, even when considering a combination of Merritt and Dorsey. Moreover, it is my opinion and judgment, as one of ordinary skill in the art, that the invention of claims 17-25 provides a simple solution to the longstanding problem of gender-misidentification among newborns, which problem no one else has yet been able to adequately solve.

13. I further declare that all statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Dated:

02/10/05

George H. Small, M.D., M.P.H.

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